MAY - 9 2001

K011065
PG. 1 OF 2

RICHARD WOLF
Medical Instruments Corporation

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Special 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: April 6, 2001
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913-0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: Intracorporeal Ultrasound Lithotripter, Transducer and Sonotrodes			Model number: 2271.xxx, 8954.xxx, 8959.xxx 8962.xxx, 8963.xxx
Common name: Intracorporeal Ultrasonic Lithotripter			**Classification Name:** Lithotripter, ultrasonic
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name		Manufacturer
1 K920235	1 Model 2270 Ultrasound Generator		1 Richard Wolf

1.0 Description

The Ultrasound Lithotripsy System is used for minimally invasive disintegration of kidney stones, urinary bladder stones and ureter stones. It consist of an ultrasound generator, an ultrasound transducer connected to the generator and the ultrasound probes, called sonotrodes. Access to the stone is gained endoscopically via the urethra or percutaneously

directly into the kidney. The stone is disintegrated under endoscopic view by contact with the sonotrode.

2.0 Intended Use

The ultrasound generator (US-LITHO) 2271 with transducer and sonotrodes (probes) is used in intracorporeal ultrasound lithotripsy exclusively for disintegration of kidney stones , urinary bladder stones and ureter stones under direct endoscopic view.

3.0 Technological Characteristics

The Intracorporeal Ultrasound Lithotripter 2271 with accessories is a modification of an existing ultrasound transducer to a new transducer with equivalent specifications and optimized acoustical impedance matching for improved vibration amplitude at the adapted sonotrodes. The new devices have the same fundamental scientific technology and intended use as the predicate device.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the equivalent devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing devices sold by Richard Wolf.

5.0 Performance Data

The Intracorporeal Ultrasound Lithotripter System was tested according to standards UL2601 and IEC 601-1, at an independent test house DEKRA-ITS in Stuttgart, Germany

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: Robert L. Casarsa Date: Apr 5, 2001

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2001

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Co.
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K011065
Intracorporeal Ultrasound Lithotriptor, Model 2271.004
Ultrasound Transducer, Model 2271.501
Ultrasound Probes (Sonotrodes), 8954.xxx, 8959.xxx, 8962.xxx, and 8963.xxx
Dated: April 6, 2001
Received: April 9, 2001
Regulatory Class: II
21 CFR §876.4480/Procode: 78 FFK

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number (if known): K011065

Device Name: Intracorporeal Ultrasound Lithotripter System

Intended Use:

The Intracorporeal Ultrasound Lithotripter System serves to disintegrate kidney stones, urinary bladder stones and ureter stones under direct endoscopic view. The use of this device for purposes other than the above is not permitted.

Contraindications: Contraindications directly related to the product are presently unknown. On the basis of the patient's general condition the physician in charge must decide whether the planned use is possible or not. For further information see the latest medical literature.

Combinations: The Ultrasound Lithotriptor consisting of Ultrasound Generator 2271, transducer and sonotrode may only be used in conjunction with a suitable suction device, e.g. suction pump. To ensure sufficient cooling of the transducer and the sonotrode, make sure that the suction can provide an adjustable vacuum of up to -0.6 bar on a continuous basis.

The Richard Wolf "Suction Pump 2207" is specifically designed for use with the ultrasound lithotriptor and provides ideal conditions for the use of this device. If a different suction pump or suction device (different manufacture) is used, the operator/user must check whether the suction device features a controllable, adjustable vacuum, which meet requirements.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011065

Prescription Use ✓ OR Over-The Counter ____
Per 21 CFR 801.109